REMARKS

The Pending Claims:

Claims 12-30 and 56-66 are pending in this application. Claims 12-30 and 56-66 are directed to a method of treating irritable bowel syndrome, fibromyalgia, chronic fatigue syndrome, depression, attention deficit/hyperactivity disorder, an autoimmune disease, or Crohn's disease.

The Office Action and Applicant's Response

The Examiner acknowledged that Applicant's amendment, received January 23, 2002 (Paper No. 14; mailed by Applicant on December 31, 2001) has been received and entered. She noted that Claims 27, 29 and 56-57 were amended.

The Examiner stated that claims 12-30 and 56-58 are pending in the instant application. Applicant is puzzled, because in the previous Office Action (issued August 29, 2001), Examiner Fields stated that Claims 12-30 and 56-66 are pending (at page 2); this would indeed be consistent with Applicant's cancellation of Claims 1-11 and 31-55, in Applicant's response to Office Action and election of designated claim Group II, which Applicant mailed April 23, 2001. Applicant has not subsequently cancelled any other claims, and therefore Applicant believes that Claims 12-30 and 56-66 are pending in the above-captioned application. Clarification is respectfully requested from the Examiner.

In the pending Office Action, the Examiner stated that the rejection of Claims 12-30 and 56-58, under 35 U.S.C. 112, second paragraph, in recitation of "SIBO" is withdrawn in view of Applicant's amendment to the claims.

The Examiner also stated that the rejection of Claims 12 and 27, under 35 U.S.C. 112, second paragraph, in recitation of "substantially simultaneously" is withdrawn in view of Applicant's amendment to the claims.

The Examiner cited the following grounds of rejection.

A. Rejections under 35 U.S.C. § 112, second paragraph

The Examiner maintained the rejection of Claims 12-30 and 56-58, under U.S.C. § 112, second paragraph, for the recitation of "whereby the symptom(s) is improved" (e.g., last line of Claim 12). She stated that without a clear definition of what constitutes an improvement, a skilled artisan would be unable to replicate the claims. In particular the Examiner stated the following reasons:

Applicants assert that the limitation of "improved" is clear based on the applicants disclosures in the specification. Applicants further assert that the specification teaches that ..."improvement in a symptom(s) is typically determined by self-reporting by the human subject, for example by VAS scoring or other questionnaire". Applicants further assert that the skilled artisan would understand the meaning of "improved".

Applicants arguments have been carefully considered but not deemed persuasive.

As stated previously, one skilled in the art would be unable to determine the meets and bounds of such a limitation. As the applicant has indicated in the response, the specification teaches that an improvement in a symptom(s) is typically determined by self-reporting by the human subject. If the patients and questionnaires vary the improvement indicated by each patient and/or questionnaire would also vary. Without a clear definition as to what constitutes as an improvement one of skill in the art would be unable to replicate the claims.

Applicant strongly disagrees that the limitation "whereby the symptom(s) is improved" is unclear merely because for certain symptoms, e.g., the perception of pain, constipation or the number of days spent in bed for IBS patients, it is common and recognized practice in the art to measure improvement subjectively, based on a patient's self-reporting.

First, the Examiner has failed to relate to the disclosures of the specification that provide objective clinical measures or physical observations to many symptoms. As Applicant has previously noted (Response to Office Action, which Applicant mailed December 31, 2001), the specification, at page 20, line 6 through page 21, line 2, cites suitable diagnostic criteria for irritable bowel syndrome, chronic fatigue syndrome, fibromyalgia, depression, ADHD, SLE, multiple sclerosis, and Crohn's disease. Notably, e.g., at page 20, lines 8-10, the specification directs the skilled artisan to the art-recognized Rome criteria for irritable bowel syndrome (IBS) (Thompson *et al.*, *Irritable bowel syndrome: pathogenesis and management*, Lancet 341:1569-72 [1993]).

Moreover, at page 29, at about lines 12-26, the specification particularly states:

> . . . Improvement in academic, professional, or social functioning, e.g., in cases of ADHD or depression can also be reported by others or can be observed by the clinician. Improvement (increase) in pain threshold, e.g., in subjects diagnosed with fibromyalgia, can be measured digitally, for example, by tender point count, or mechanically, for example, by dolorimetry. (F. Wolfe *et al.*, *Aspects of Fibromyalgia in the General Population: Sex, Pain Threshold, and Fibromyalgia Symptoms*, J. Rheumatol. 22:151-56 [1995]). Improvement in visceral hypersensitivity or hyperalgesia can be measured by balloon distension of the gut, for example, by using an electronic barostat. (B.D. Nabiloff *et al.*, *Evidence for two distinct perceptual alterations in irritable bowel syndrome*, Gut 41:505-12 [1997]). Some improvement(s) in symptoms, for example systemic lupus erythematosus symptoms, such as rashes, photosensitivity, oral ulcers, arthritis, serositis, or improvements in the condition of blood, kidney or nervous system, can be determined by clinical observation and measurement.

Thus, the specification as originally filed teaches numerous examples of relatively objective techniques by which a clinician can measure improvement in a patient's symptoms after treatment, compared to before treatment, including tender point count, dolorimetry, balloon distension of the gut, electronic barostat, the clinical observation of rashes, photosensitivity, oral ulcers, arthritis, serositis, or [known assays] of conditions of blood, kidney or nervous system, (also third-party reporting of academic, professional, or social functioning in ADHD). The specification, as originally filed teaches these and other objective criteria for determining whether a "symptom is improved", as recited, e.g., in Claim 12.

The Examiner has chosen to focus on the statement in the specification, at page 29, at about line 12, ". . . Improvement in a symptom(s) is typically determined by self-reporting by the human subject, for example by VAS scoring or other questionnaire." This statement is of particular, but not exclusive, relevance to irritable bowel syndrome (IBS). It has long been recognized in the art that for many symptoms of IBS-- such as abdominal pain, feelings of uncomfortable intestinal distension, feelings of depression or

anxiety, abnormal bowel frequency-- the best available clinical information comes from patient self-reporting. Accordingly, patient questionnaires and other patient self-reporting scales have been, and continue to be, employed by skilled artisans to assess a patient's response to treatment for IBS symptoms. For example, Farup *et al.*, employed a self-reporting visual analogue scale (VAS) to determine that "cisapride *improves symptoms* in [IBS] patients with idiopathic constipation." (Emphasis added)(Farup, PG *et al.*, *The symptomatic effect of cisapride in patients with irritable bowel symndrome and constipation*, Scand. J. Gastroenterol. 33(2):128-31 [Feb. 1998], abstract appended as **Exhibit A**). Similarly, Noor *et al.* employed "a visual analogue scale before and after treatment" to assess symptoms. (Noor, N. *et al.*, *Effects of cisapride on symptoms and postcibal small-bowel motor function in patients with irritable bowel syndrome*, Scand. J. Gastroenterol. 33(6):605-11 [June 1998], abstract appended as **Exhibit B**). Francis *et al.* recognized the need for, and provided clinical validation for, a self-reporting severity scoring system to assess, *inter alia*, pain, distension, bowel dysfunction, and quality of life/global well-being, as "a valuable instrument in helping to meet the many challenges offered by irritable bowel syndrome." (Francis, CY *et al.*, *The irritable bowel severity scoring system: a simple method of monitoring irritable bowel syndrome and its progress*, Aliment. Pharmacol. Ther. 11(2):395-402 [Apr. 1997], abstract appended as **Exhibit C**). Additional post-filing date references also validate the use of self-assessment instruments for evaluating the symptoms of IBS patients. (e.g., Sperber, AD *et al.*, *Use of the Functional Bowel Disorder Severity Index [FBDSI] in a study of patients with the irritable bowel syndrome and fibromyalgia*, Am. J. Gastroenterol. 95(4):995-8 [Apr 2000], abstract appended as **Exhibit D**; Drossman, DA *et al.*, *Further validation of the IBS-QOL: a disease-specific quality-of-life questionnaire*, Am. J. Gastroenterol. 95(4):999-1007 [Apr 2000], appended as **Exhibit E**; Groll, D *et al.*, *The IBS-36: a new quality of life measure for irritable bowel syndrome*, Am. J. Gastroenterol. 97(4):962-71 [Apr 2002], appended as

Exhibit F).

These references demonstrate that, contrary to the Examiner's assertion, skilled artisans know that a self-assessment instrument (e.g., questionnaire or VAS) is useful and provides internal controls by which the improvement of an individual patient's symptom(s) over time can be effectively assessed. Although self-reporting questionnaires or self-assessment scales that are actually employed may vary by practioner, clinical institution, or study, it is well known to the skilled artisan that if the *same* self-assessment instrument is employed *both before and after* treatment for each patient, a determination can be made that a patient's "symptom is improved."

Therefore, Applicant asserts that the skilled artisan is indeed capable of knowing what constitutes an "improvement" in the symptoms of the human subject. The Examiner is respectfully requested to withdraw the rejection of Claims 12-30 and 56-58 on this ground.

B. Rejections under 35 U.S.C. § 102(b)

The Examiner maintained the rejection of Claims 12-30 and 56-58 for a purported lack of novelty over: (1) McCann *et al.* (U.S. Patent No. 5,599,795); (2) Sandborn (U.S. Patent No. 5,691,343); and (3) Becker *et al.* (U.S. Patent No. 5,612,366). The Examiner stated the following reasons:

... Applicants assert that the McCann et al reference is directed to a method of treating idiopathic inflammatory bowel disease (IIBD) and the applicants invention is directed at a method of treating irritable bowel syndrome (IBS).

Applicants arguments have been carefully considered but not deemed persuasive. The claims recites a method of treating irritable bowel syndrome, fibromyalgia, chronic fatigue syndrome, depression, attention deficit/hyperactivity disorder, an autoimmune disease, or Chrohn's disease. McCann et al. disclose a method of treating Chrohn's disease. The Examiner agrees with the applicant that McCann et al. also discloses a method of treating idiopathic inflammatory bowel disease (IIBD) however, irritable bowel syndrome (IBS) and IIBD belong to a family of overlapping clinical diseases/disorders...

... Applicants assert that the Sandborn et al. reference is directed to a method of treating Inflammatory Bowel Disease (IBD) not IBS. Applicants have also asserted that Sandborn et al. fails to describe the use of 5-aminosalicylate in the treatment of IBS ...

... As stated above, the claims recite a method of treating irritable bowel syndrome, fibromyalgia,

chronic fatigue syndrome, depression, attention deficit/hyperactivity disorder, an autoimmune disease, or Chrohn's disease. Sandborne et al. like McCann et al. disclose a method of treating Chrohn's disease. Because IBS and IBD belong to a family of overlapping clinical diseases/disorders and because the claims recite that the invention is directed to IBS or Crohn's Disease (IBD) the prior art anticipates the claimed invention. Regarding the argument that Sandborn et al. fails to describe the use of 5-aminosalicylate in the treatment of IBS, Sandborn et al teaches of administering 5-aminosalicyclate to patients with IBD (i.e. Crohn's Disease). Moreover, such a treatment is well known in the art . . .

. . . Regarding the argument that the applicants claimed method includes the step of detection, it can be reasonably concluded that if a method of treatment is administered, the disease and/or disorder had to be detected prior to treatment. Since the specification teaches that any suitable method may be used for detection, the prior art anticipates the claimed invention . . .

. . . The invention is directed to a method of treatment. As stated above it can be reasonably concluded that if a method of treatment is administered, the disease and/or disorder had to be detected. This step is therefore not novel but obvious. The specification teaches that any suitable method may be used for detection.

A claim is anticipated only if each and every element as set forth in the claim is found in a single prior art reference. *Verdgaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Applicant strongly disagrees that the cited references negate the novelty of Applicant's claimed method. Applicant's claimed method includes the steps of "detecting the presence of small intestinal bacterial overgrowth in a human subject having at least one symptom associated with a suspected diagnosis of irritable bowel syndrome, etc. . .; and at least partially eradicating the bacterial overgrowth" (e.g., Claim 12 and claims directly or indirectly dependent therefrom). All of the cited references fail to describe or even suggest a step of "detecting the presence of small intestinal bacterial overgrowth . . ." Thus, McCann *et al.*, Sandborn, and Becker *et al.* all fail to anticipate each and every element as set forth in Applicant's Claims 12-30 and 56-58.

Repeatedly, the Examiner asserted in the pending Office Action that "The specification teaches that any suitable method may be used for detection." This assertion mischaracterizes the teachings of the specification, as originally filed. The specification actually teaches, e.g., at page 18, lines 12-13, "Specifically, the present

methods are based on the detection and treatment of a unified cause . . ., i.e., small intestinal bacterial overgrowth (SIBO)." The specification further teaches, at page 19, line 28 through page 20, line 3, that ". . . the detection of SIBO in the human subject corroborates the suspected diagnosis held by a qualified medical practitioner who, prior to the detection of SIBO in the human subject, suspects from more limited clinical evidence that the human subject has irritable bowel syndrome, fibromyalgia, chronic fatigue syndrome, depression, ADHD, an autoimmune disease, or Crohn's disease." Finally, at page 21, lines 3-5, the specification states, "Detecting *the presence of small intestinal bacterial overgrowth (i.e., SIBO)* is accomplished by any suitable method. For example, one preferred method of detecting SIBO is breath hydrogen testing." (Emphasis added). Thus, the specification clearly teaches that any suitable method may be used for detection *of SIBO*. The Examiner has failed to include the entire context, and consequently she has mischaracterized the specification's teachings.

Since McCann *et al.*, Sandborn, and Becker *et al.* all failed to describe or even suggest detecting the presence of small intestinal bacterial overgrowth (SIBO) by any method whatsoever, they failed to anticipate Applicant's claimed method.

Therefore, the Examiner is respectfully requested to withdraw the rejection of Claims 12-30 and 56-58 on this ground.

CONCLUSION

In view of the above amendments and remarks, it is submitted that this application is now ready for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call

the undersigned attorney at (213) 896-6665.

Respectfully submitted,

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1: Scand J Gastroenterol 1998 Feb;33(2):128-31

The symptomatic effect of cisapride in patients with irritable bowel syndrome and constipation.

Farup PG, Hovdenak N, Wetterhus S, Lange OJ, Hovde O, Trondstad R.

Dept. of Medicine, Gjovik County Hospital, Norway.

BACKGROUND: Cisapride improves symptoms in patients with idiopathic constipation. This trial compares the effect of cisapride with that of placebo in patients with irritable bowel syndrome (IBS) and constipation. METHODS: Seventy patients were randomized to 12 weeks' treatment with 5 mg cisapride three times daily or placebo in a double-blind trial. The dose could be doubled after 4 weeks in patients without satisfactory improvement. The patients scored their symptoms on a 100-mm visual analogue scale (VAS) (0 = best, 100 = worst), and the investigators evaluated the symptomatic effect. RESULTS: The dose was doubled in 17 and 23 patients in the cisapride and placebo groups, respectively, after 4 weeks. The patients' mean VAS score for global evaluation of IBS symptoms in the cisapride and placebo groups was 73 and 71 mm, respectively, at the start of treatment and 47 and 41 mm at the end. The difference between cisapride and placebo at the end was 6 mm in favour of placebo (95% confidence interval (CI), -6, 18) (NS). The investigators evaluated the effect as good or excellent in 39.2% and 58.8% in the cisapride and placebo groups, respectively. The difference in favour of placebo was 19.5% (95% CI, -5, 44) (NS). Nor were any statistically significant differences seen between cisapride and placebo in the other effect factors. CONCLUSIONS: The trial seems to exclude a clinically significant effect of 15-30 mg cisapride daily in patients with IBS and constipation during a 12-week treatment period.

Publication Types:
Clinical Trial
Controlled Clinical Trial
Randomized Controlled Trial

PMID: 9517521 [PubMed - indexed for MEDLINE]

1: Scand J Gastroenterol 1998 Jun;33(6):605-11

Effects of cisapride on symptoms and postcibal small-bowel motor function in patients with irritable bowel syndrome.

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BACKGROUND: Irritable bowel syndrome is a common cause of abdominal pain and discomfort and may be related to disordered gastrointestinal motility. Our aim was to assess the effects of long-term treatment with a prokinetic agent, cisapride, on postprandial jejunal motility and symptoms in the irritable bowel syndrome (IBS). METHODS: Thirty-eight patients with IBS (constipation-predominant, n = 17; diarrhoea-predominant, n = 21) underwent 24-h ambulatory jejunal manometry before and after 12 week's treatment [cisapride, 5 mg three times daily (n = 19) or placebo (n = 19)]. RESULTS: In diarrhoea-predominant patients significant differences in contraction characteristics were observed between the cisapride and placebo groups. In cisapride-treated diarrhoea-predominant patients the mean contraction amplitude was higher (29.3 +/- 3.2 versus 24.9 +/- 2.6 mm Hg, cisapride versus placebo ($P < 0.001$); pretreatment, 25.7 +/- 6.0 mm Hg), the mean contraction duration longer (3.4 +/- 0.2 versus 3.0 +/- 0.2 sec, cisapride versus placebo ($P < 0.001$); pretreatment, 3.1 +/- 0.5 sec), and the mean contraction frequency lower (2.0 +/- 0.2 versus 2.5 +/- 0.4 cont./min, cisapride versus placebo ($P < 0.001$); pretreatment, 2.5 +/- 1.1 cont./min] than patients treated with placebo. No significant differences in jejunal motility were found in the constipation-predominant IBS group. Symptoms were assessed by using a visual analogue scale before and after treatment. Symptom scores relating to the severity of constipation were lower in cisapride-treated constipation-predominant IBS patients [score, 54 +/- 5 versus 67 +/- 14 mm, cisapride versus placebo ($P < 0.05$); pretreatment, 62 +/- 19 mm]. Diarrhoea-predominant IBS patients had a higher pain score after cisapride therapy [score, 55 +/- 15 versus 34 +/- 12 mm, cisapride versus placebo ($P < 0.05$); pretreatment, 67 +/- 19 mm]. CONCLUSION: Cisapride affects jejunal contraction characteristics and some symptoms in IBS.

Publication Types:
Clinical Trial
Randomized Controlled Trial

PMID: 9669632 [PubMed - indexed for MEDLINE]

1: Aliment Pharmacol Ther 1997 Apr;11(2):395-402

The irritable bowel severity scoring system: a simple method of monitoring irritable bowel syndrome and its progress.

Francis CY, Morris J, Whorwell PJ.

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BACKGROUND: The clinical assessment and investigation of irritable bowel syndrome would be greatly facilitated by the introduction of a simple, easy to use severity scoring system. Such a system, developed in our department over a number of years, has been submitted to validation in a total of 141 patients and 40 healthy controls. METHODS: The system, incorporating pain, distension, bowel dysfunction and quality of life/global well-being, was assessed for its ability to reliably score patients previously classified as mild, moderate or severe. The reproducibility and sensitivity to change of the system was also assessed. RESULTS: The maximum achievable score was 500. Mild, moderate and severe cases were indicated by scores of 75 to 175, 175 to 300 and > 300 respectively. Controls scored below 75 and patients scoring in this range can be considered to be in remission. There was a highly significant difference between controls and patients as a whole ($P = 0.0001$) as well as significant differences ($P < 0.01$) between all severity categories. Scores repeated within 24 h were very reproducible and sensitivity to change was also extremely good ($P < 0.001$) with a change of 50 reliably indicating improvement. CONCLUSION: These results suggest that this scoring system should prove to be a valuable instrument in helping to meet the many challenges offered by irritable bowel syndrome.

PMID: 9146781 [PubMed - indexed for MEDLINE]

1: Am J Gastroenterol 2000 Apr;95(4):995-8

Use of the Functional Bowel Disorder Severity Index (FBDSI) in a study of patients with the irritable bowel syndrome and fibromyalgia.

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OBJECTIVE: The purpose of this study was to evaluate the utility of the Functional Bowel Disorder Severity Index (FBDSI) as a measure of severity of disease among patients with the irritable bowel syndrome (IBS) and matched controls. METHODS: A total of 75 IBS patients and 69 matched controls completed questionnaires on bowel symptoms, health status, quality of life, psychological distress, concerns, anxiety, and sense of coherence. All participants also were tested for fibromyalgia (FS), a functional disorder of the musculoskeletal system. All participants were administered a questionnaire that included the FBDSI. On the basis of their responses to the questionnaire, the controls were subdivided as healthy controls (n = 48) or IBS nonpatients (n = 21). On the basis of the FS classification, 75 IBS patients were subdivided as IBS only (n = 50) or IBS and FS combined (n = 25). RESULTS: The mean FBDSI score was higher for the IBS patients than the controls (100.5+/-12.7 and 23.5+/-3.9, respectively; $p < 0.001$). IBS nonpatients had an intermediate score of 42.3+/-18.0. Patients with both IBS and fibromyalgia had the highest mean FBDSI score: 138.8+/-31.5. There was no association between FBDSI and age or gender, but FBDSI was significantly associated with other measures of health status. CONCLUSIONS: An association was found between the FBDSI and IBS patient status: IBS nonpatients, patients with IBS only, and patients with both IBS and fibromyalgia had increasingly severe scores. The results provide support for the validity of FBDSI as a measure of illness severity in functional gastrointestinal disorders.

PMID: 10763949 [PubMed - indexed for MEDLINE]

1: Am J Gastroenterol 2000 Apr;95(4):999-1007

Further validation of the IBS-QOL: a disease-specific quality-of-life questionnaire.

Drossman DA, Patrick DL, Whitehead WE, Toner BB, Diamant NE, Hu Y, Jia H, Bangdiwala SI.

UNC Center for Functional GI and Motility Disorders, Division of Digestive Diseases, University of North Carolina, Chapel Hill 27599-7080, USA.

OBJECTIVE: There has been growing interest in the investigation of health-related quality of life (HRQOL) among patients with gastrointestinal (GI) disorders. We recently reported on the development and preliminary validation of the IBS-QOL, a specific quality-of-life measure for irritable bowel syndrome (IBS). The aim of this study was to determine the longitudinal construct validity (responsiveness) of the IBS-QOL. METHODS: Female patients enrolled in a multicenter treatment trial for functional bowel disorders were studied pre- and posttreatment with the IBS-QOL and other health status measures. Based on the response to treatment for several variables (pain/14-day score, daily function, and days in bed/3 months), patients were stratified into Responders, Partial Responders, and Nonresponders. Change scores in the IBS-QOL were then statistically compared with changes in the other variables to determine their correlation and whether Responders were significantly different from non- and Partial Responders on the IBS-QOL. RESULTS: There was a significant correlation between change scores on the IBS-QOL and the other measures of treatment effect (Pain/14 days, $r = 0.25$, $p < 0.002$; Sickness Impact Profile [SIP] Total Score, $r = 0.28$, $p < 0.0004$). In addition, the IBS-QOL scores significantly differentiated Responders from Nonresponders for most of the variables tested (regression trend test for Pain/14 days, $p < 0.04$; SIP Total, $p < 0.0001$; SIP Physical, $p < 0.0001$; SIP Psychosocial, $p < 0.002$, and SIP Eating, $p < 0.04$). CONCLUSION: The IBS-QOL is responsive to treatment in a referral-based clinical population of patients with functional bowel disorders.

Publication Types:
Clinical Trial
Multicenter Study
Randomized Controlled Trial

PMID: 10763950 [PubMed - indexed for MEDLINE]

1: Am J Gastroenterol 2002 Apr;97(4):962-71

The IBS-36: a new quality of life measure for irritable bowel syndrome.

Groll D, Vanner SJ, Depew WT, DaCosta LR, Simon JB, Groll A, Roblin N, Paterson WG.

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OBJECTIVE: We aimed to develop and validate a quality of life instrument for patients with irritable bowel syndrome (IBS). METHODS: Using focus groups, existing questionnaires, and literature reviews, five IBS patients and nine gastroenterologists compiled and pilot tested for content validity a 70-item questionnaire. The questionnaire was then administered to 107 IBS patients, and using these data, the 70-item questionnaire was reduced to 36 questions through statistical and consensus methodology. The IBS-36 questionnaire was tested for construct validity, reliability, reproducibility, and responsiveness using a gold standard of structured interviews by three gastroenterologists, the Medical Outcomes Study Short Form Quality of Life Questionnaire, and the Coping Resource Inventory. RESULTS: The IBS-36 consists of 36 questions scored on a 7-point Likert scale. It has a very high internal consistency (Cronbach's alpha = 0.95) and a high test-retest reliability (Spearman's r = 0.92) and correlates as hypothesized with the Medical Outcomes Study Short Form Quality of Life Questionnaire ($p < 0.001$), McGill pain scores ($p < 0.001$), and IBS patient-reported sleep, symptom, and pain scores (ps = 0.030, <0.001, and <0.001, respectively). CONCLUSIONS: The IBS-36 addresses all areas of quality of life affected by IBS and is easy to administer and score. The IBS-36 is a well-validated, condition-specific quality of life measure for IBS patients that is sensitive to clinical intervention and highly correlated with established quality of life measures and patient-reported symptom scores.

Publication Types:
Validation Studies

PMID: 12003433 [PubMed - indexed for MEDLINE]